UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,090	02/25/2004	Yoshihiro Takami	249424US0	8516

22850 7590 10/27/2005

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
AFREMOVA, VERA	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 10/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/785,090	TAKAMI, YOSHIHIRO	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 9-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/25/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the Group II, claims 4-8, in the reply filed on 8/11/2005 is acknowledged. The traversal is on the ground(s) that there is no sufficient prove that products such as acellular dermal matrix (group II, claims 4-8) and composite cultured skin (group III, claim 14) are different and that there is not sufficient prove that products can be made by different methods. This is not found persuasive because acellular dermal matrix and skin product are different as claimed and they are also distinct because claimed "cultured" skin is a living product but acellular collagen matrix is dead material. Furthermore, an acellular collagen can be made by another method such as tissue treatment with several enzymes including carbohydrate splitting enzymes, for example: US 4,399,123 (abstract).

Thus, the requirement is still deemed proper and is therefore made FINAL.

Claims 1-3 and 9-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 8/11/2005.

Claims 4-8 are under examination in the instant office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless–
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,399,123 (Oliver et al.).

Claims are directed to an acellular dermal matrix that is decellularized or does not contain cells. Some claims are further drawn to the acellular dermal matrix derived from human or pig skin.

US 4,399,123 (Oliver et al.) discloses an acellular dermal matrix made from human and from pig skin (examples 1 and 6). The human or pig dermis is treated with enzymes including trypsin and amylase in saline and buffer solutions. The final product is purified so that all cellular elements are removed (col. 1, lines 59-61) and, thus, the final product of US 4,399,123 is "decellularized" or it does not contain cells as required for the claimed product. Therefore, the final products as disclosed and as claimed are characterized by identical structure and they are considered to be identical. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. MPEP 2113.

2. Claims 4, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Takami et al. (IDS reference; Jpn. J. Burn. Inj. December 2000, Vol. 26, No. 5, pages 39-45).

Claims are directed to an acellular dermal matrix that is decellularized by treatment with protease and surfactant. Some claims are further drawn to the surfactant such as polyoxyethylene p-t-octylphenyl ether (same as Triton X-100, see specification page 12, line 17). Some claims are further drawn to the acellular dermal matrix derived from human skin.

The reference by Takami et al. discloses an acellular dermal matrix made from human skin and decellularized by treatment with protease such as dispase and surfactant such as Triton

X-100 (see entire document including abstract). Thus, the cited reference clearly anticipates the claimed invention.

3. Claims 4-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Jiang Duyin et al. {Chinese Journal of Burns, (2002 Feb) 18 (1) 15-8}.

Claims are directed to an acellular dermal matrix that is decellularized by treatment with protease and surfactant. Some claims are further drawn to the protease such as trypsin. Some claims are further drawn to the surfactant such as polyoxyethylene p-t-octylphenyl ether (same as Triton X-100, see specification page 12, line 17). Some claims are further drawn to the acellular dermal matrix derived from porcine skin.

The reference by Jiang Duyin et al. discloses an acellular dermal matrix made from pig skin that is decellularized by treatment with trypsin and Triton X-100 (entire document including English abstract, in particular). Thus, the cited reference clearly anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takami et al. (IDS reference; Jpn. J. Burn. Inj. December 2000, Vol. 26, No. 5, pages 39-45) and Jiang Duyin

et al. {Chinese Journal of Burns, (2002 Feb) 18 (1) 15-8} taken with US 4,399,123 (Oliver et al.) and US 5,336,616 (Livesey et al.).

Claims are directed to an acellular dermal matrix that is decellularized by treatment with protease and surfactant. Some claims are further drawn to the surfactant such as polyoxyethylene p-t-octylphenyl ether (same as Triton X-100, see specification page 12, line 17). Some claims are further drawn to the acellular dermal matrix derived from human skin or from pig skin.

The cited references by Takami et al. and by Jiang Duyin et al. are relied upon as explained above. They both teach an acellular dermal matrix that is decellularized by treatment with protease and surfactant. The same surfactant Triton X-100 is used for making both dermal matrices. The reference by Takami et al. teaches the use of dispase as protease for obtaining human dermal matrix. The reference by Jiang Duyin et al. teaches the use of trypsin as protease for obtaining pig dermal matrix.

Thus, the reference are missing particular disclosure about human skin derived preparation of acellular dermal matrix that is decellularized with trypsin.

However, both dispase and trypsin are alternative or equivalent proteases that are used for obtaining acellular dermal matrices as taught by US 5,336,616 (col. 9, lines 53-56) and that are applicable for dermal matrix preparation derived from animal skin including human (col.23, line 9). Furthermore, US 4,399,123 (Oliver et al.) demonstrates the use of trypsin for both human and pig dermis derived preparations that are free of cells and cellular materials (col.4, lines 56-63 and examples 1 and 6).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to obtain human skin derived preparation of acellular dermal

matrix that is treated with trypsin with a reasonable expectation of success in decellularizing human dermal matrix and reducing its antigenic properties as adequately taught and suggested by the cited references. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

October 25, 2005

V. Afremova

VERA AFREMOVA

PRIMARY EXAMINER